



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Start-Up Option Exclusive License: The Development of Liposomal Therapeutic Agents for the Treatment of Human Epithelial Cancers and Liposarcomas**

**AGENCY:** National Institutes of Health, Public Health Service, HHS

**ACTION:** Notice

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to ZoneOne Pharma, Inc., of an exclusive evaluation option license to practice the inventions embodied in the following US Patent (and all foreign counterparts): Serial No. 6,890,917 entitled, “Geldanamycin Derivative and Method of Treating Cancer Using Same” [HHS Ref. E-050-2000/0-US-15]. The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide, and the field of use may be limited to:

The pharmaceutical use in humans of 17-dimethylaminoethylamino-17-demethoxygeldanamycin (“17-DMAG”) as a liposome-encapsulated drug, alone

or in combination with other agents, for the treatment of the following types of cancer: ovary, pancreas, metastatic skin, head and neck, colon, kidney, non-small cell lung, or liposarcoma.

Upon the expiration or termination of the exclusive evaluation option license, ZoneOne Pharma, Inc., will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

**DATE:** Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

**ADDRESS:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Patrick McCue, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5560; Facsimile: (301) 402-0220; E-mail: [mccuepat@mail.nih.gov](mailto:mccuepat@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** This invention concerns 17-DMAG, the first water-soluble analog of 17-AAG, a less toxic and more stable analog of the antitumor antibiotic geldanamycin.

The prospective exclusive evaluation license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive evaluation license, and a subsequent exclusive commercialization license, may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

March 8, 2013  
Date

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Richard U. Rodriguez,  
Director  
Division of Technology Development & Transfer  
Office of Technology Transfer  
National Institutes of Health